# Participant Information Sheet

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| **Study Title** | **N**ear **I**nfrared spectroscopy for **M**onitoring brain **O**xygenation: a single-centre randomised controlled trial of freshly ir**rad**iated versus standard red cell transfusion for treatment of anaemia of prematurity (**NIMO-Rad**) |
| **Locality** | Wellington Regional Hospital<br>Neonatal Intensive Care Unit |
| **Coordinating Investigator** | Dr. Maria Saito-Benz |
| **Contact Number** | 021570609 |
| **Ethics Reference** | 17/CEN/202 |

**Introduction:**
As the person responsible for your baby, you are invited to consider your baby's participation in this study. We are approaching you because your baby was born premature, has a condition called anaemia, and your doctors think that your baby may benefit from blood transfusion.

Thank you for taking time to read this information sheet. It contains detailed information about the study, and its purpose is to explain to you as openly and clearly as possible, the background and all the steps involved in the study. Please read all pages carefully, and feel free to ask questions about any of the information. You may wish to talk to your friends, family, whānau, or healthcare providers about the study.

Participation in this study is voluntary. Whether you wish to take part or not is entirely up to you, and you do not need to give a reason for your decision. You and your baby's medical care and relationship with the hospital will not be affected in any way by your decision.

If you agree for your baby to take part in this study, you will be asked to sign a consent form. By signing it you are telling us that you:

- Understand what you have read
- Consent your baby to take part in the study
- Consent to your baby participating in the study steps that are described
- Consent to the use of your baby's personal and health information as described

**Purpose of the study:**
Currently **all** red blood cells given to premature babies are irradiated before transfusion. This is a safety measure and irradiation prevents a rare but potentially serious complication of blood transfusion (called the 'graft-versus-host disease'). Once red blood cells are irradiated, they are stored in the Blood Bank for a variable length of time before they are used.

Findings from our recent study suggests storage after irradiation may affect the quality and/or function of red blood cells given to premature babies. Therefore, the aim of this study is to find out if freshly irradiated red blood cells (i.e. on the day of transfusion) are more effective in treating anaemia of prematurity than red blood cells irradiated and then stored before use. Red blood cells carry oxygen to important organs such as the brain, and so as part of the study we will be looking at oxygen levels in your baby before and after transfusion.

**Who are we looking for?**
We are looking for premature babies (born younger than 34 weeks gestation) in Wellington NICU, who are at least 2 weeks old and are receiving blood transfusion for anaemia.

**What does the study involve?**
Your baby will be allocated to receiving transfusion of either freshly irradiated red blood cells ('intervention group') or red blood cells that are irradiated and stored as per current practice ('control group'). This allocation will be done randomly (i.e. by chance), and neither you, medical team, nor study investigators will know which group your baby is allocated to until the study is completed.

*Measuring oxygen levels in your baby*
Oxygen levels will be measured using portable and non-invasive monitors (Near Infrared Spectroscopy and pulse oximeter) for 3 hours just before, just after, 1 day and 5 days after transfusion. One small and soft probe and containing LED light emitters and receivers will be placed on your baby's forehead and one on your baby's hand or foot during the study periods. These monitors are safe to use in premature babies.

*Blood test before transfusion*
It is a standard practice for your baby to have a blood test ('venous full blood count') before transfusion. However, if this is not done within 24hrs of transfusion we would like to perform a one-off blood test. We will need 0.35ml of blood (less than 1/10 of a teaspoon). This will be done by a skilled practitioner using appropriate comfort measures (e.g. sucrose) at the same time as a cannula for transfusion is inserted to avoid any additional discomfort.

Your baby may receive more than one blood transfusion while in Wellington NICU. If transfusion episodes are more than 1 week apart, your baby may be eligible to take part in the study more than once. Please let us know by indicating on the consent form if you are happy for us to study all eligible transfusions. Each transfusion will be allocated to the intervention or control groups randomly (i.e. by chance).

**Confidentiality of health information:**
If you choose to participate in the study, we will inform doctors and nurses looking after your baby (including your GP) of your baby's participation in the study. All relevant clinical information gathered as part of the study will be treated with confidence and no information that could identify you or your baby will be released to any person not associated directly with the study. All study records will be kept securely and electronically in a databank. All study records will be stored until your child's 16th birthday.

The results of the study may eventually be published in medical journals or presented at professional meetings, but you and your baby will not be identified in any way.

**Benefits of the study:**
If your baby is allocated to receiving freshly irradiated red blood cells, it is possible that transfusion may lead in a greater improvement in oxygen level in the brain and your baby may have less desaturation episodes after transfusion.

**Risks of the study:**
Because it is a standard practice to irradiate red blood cells before transfusion your baby will not be put at risk by receiving freshly irradiated red blood cells. However, it is possible that freshly irradiating red blood cells makes no difference to your baby's health. Your baby may need an additional one-off blood test which will be performed at the same time as cannula insertion to avoid additional bruising and/or discomfort. Both pulse oximeter and NIRS are non-invasive and are safe to use in premature babies.

**Study results:**
Once the study is completed we are more than happy to send you a summary of the study findings. Please indicate your preference in the consent form whether you wish to receive the summary and how you would like us to contact you.

**Voluntary study participation and withdrawal:**
Participation in this study is voluntary, and it is entirely your decision to participate or not in this study. If you decide to participate, you are free to withdraw your baby from the study at any stage, without explanation of why you have chosen to do so and without prejudice to you and your baby's current and future treatment. You can request for any data collected from your baby to be deleted while the study is actively recruiting new participants (i.e. before investigators start analysing results).

**Compensation:**
In the unlikely event of a physical injury as the result of your baby's participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the Accident Compensation Act 2001. If you have any questions about ACC, please contact your nearest ACC office.

**Study approval:**
This study has been reviewed and approved by HDEC. If you wish to discuss the study with someone not directly involved, in particular in relation to policies, your rights as a participant, or should you wish to make a confidential complaint, you should contact Ethics Committee on 0800 4 ETHICS (0800 438 442) or hdecs@moh.govt.nz

**Further information:**
If you would like any further information about this study, please contact:

Dr. Maria Saito-Benz (Coordinating Investigator)
Email: maria.saitobenz@otago.ac.nz
Tel: 021570609

Dr. Max Berry (Principal Investigator)
Email: max.berry@otago.ac.nz
Tel: 0212449929

**Other contacts (support groups not involved in the study):**
*Independent Health and Disability Advocate:*
Free Phone: 0800 555 050
Free Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

*Māori cultural support contact:*
Whanau Care is able to provide support to patients and whanau during their time in hospital and while taking part in this study. Whanau Care service at Wellington Hospital is located in atrium (level 2).
Phone: 04 806 0948
Email: wcs@ccdhb.org.nz